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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,489	07/31/2001	Isabel Antonia Maria Van Waterschoot	01-468	9467

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,489	VAN WATERSCHOOT ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,15,18-21 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,15,18-21 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for extension of time, both filed 12/27/2004.

Claims 1-4, 6, 7, 15, 18-21, and 25 are pending. Claims 26-28 have been added. Claims 1-4, 6, 7, 15, 18-21, and 25-28 are included in the prosecution.

The following new ground of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 18, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoting lactation in female mammal by administering ARA in an edible formulation, does not reasonably provide enablement for promoting reproductive efficiency or success, or fertility. Further, the specification has enabled administering ARA in an edible formulation, but has not enabled any other route of administering ARA. Furthermore, the specification has enabled administering ARA for promoting lactation and treating of associated condition resulting from PUFA

deficiency, but has not enabled preventing of any diseases or conditions associated with PUFA deficiency. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is an edible formulation such as a dietary supplement comprising ARA by itself or in combination with and DHA and method of its use for pregnant or lactating mammals to promote lactation. The nature of the invention is complex in that it encompasses varieties of formulations comprising ARA and DHA used for multiple complex disorders having unrelated manifestations and etiology, and subsequently treated by administering the instant edible formulation. The entire specification disclosed edible formulation in form of dietary supplement, pill, tablet, capsule or gelatin capsule comprising ARA or combination of ARA and DHA used as dietary supplement to promote lactation in

lactating mammals, examples 1-6. Nowhere in the specification applicants disclosed formulations other than edible formulation, or uses other than dietary supplement for pregnant and lactating mammals. Further, the specification does not enable the promotion of reproductive efficiency or success or fertility as claimed, or preventing any disease or condition associated with PUFA deficiency.

The breadth of the claims: The claim is broad. The claim encompasses all verities of pharmaceutical compositions including oral, topical, parenteral or edible compositions. The claim encompasses promotion and/or prevention of complex disorders that may have potential causes other than those disclosed in the specification that are related to ARA and/or DHA deficiency. This may or may not be addressed by the administration of the instant edible formulation comprising ARA. For example infertility can be caused by hormonal disturbance that needs hormonal therapy; or can be caused by fallopian tube sclerosis or adhesion that needs surgical interference. Moreover, the specification is directed to dietary supplement for pregnant or lactating mammals, however, other disorders, such as infertility disorders are encompassed by the instant claims. The specification has enabled lactation promotion, but not prevention or cure of associated conditions that may encompass infant malnutrition. Further, the claims encompass all the forms of the pharmaceutical composition, while only dietary supplement is disclosed.

The state of the prior art: The state of the art does not recognize the administration of composition comprising ARA to promote reproductive efficiency or success or fertility. The state of the art recognizes the administration of dietary

supplement comprising ARA and DHA to the pregnant and lactating human and animals, US 6,200,624, but not preventing associated conditions or diseases, or their cure.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to promote reproductive efficiency or success or fertility, or on how to prevent conditions or diseases associated with PUFA deficiency is absent. No evidence is provided regarding promotion of fertility, or preventing conditions associated with PUFA deficiency. Guidance for a capsule used as dietary supplement to promote lactation is provided. Furthermore, the specification provides no guidance, in the way written description, on any pharmaceutical compositions other than dietary supplement. The specification provides guidance on edible formulation comprising DHA and/or ARA such as dietary supplement, tablet, pill or capsule, page 3, lines 13-14 of the present specification. It is not obvious from the disclosure of capsule comprising DHA and/or ARA used as a dietary supplement for pregnant and lactation mammals if other formulations for other uses will work, e.g. topical formulation comprising ARA would promote fertility in an infertile mammal. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than

the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to formulations other than edible formulation comprising ARA that promote fertility makes practicing the claimed invention unpredictable in terms of using other formulations for promoting fertility that may have causes other than fatty acid deficiency and require completely different approach.

The presence or absence of working examples: The specification discloses only edible formulation such as dietary supplement or capsule comprising ARA and/or DHA used for pregnant and lactating mammals, examples 1-6. No working examples to show formulations other than edible formulation used to promote fertility as recited in the claim. No working examples to show prevention of conditions associated with PUFA deficiency. Therefore, the specification has only enabled edible formulation in the form of capsule or dietary supplement comprising ARA and DHA for pregnant and lactating mammals.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method for promoting fertility that may have potential causes other than ARA and DHA deficiency, or preventing conditions associated with PUFA deficiency without guidance from the

specification or the prior art. Also, the practitioner would turn to trial and error experimentation to practice the instant method in term of other formulations other than the edible formulation for promoting lactation without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Response to Arguments

3. Applicant's arguments filed 09/22/2005 have been fully considered but they are not persuasive. Applicants traverse the rejection under 112 first paragraph by arguing that one of relative skill in the art would understand the promotion of lactation and/or reproductive efficiency of fertility are not "multiple complex disorders having unrelated manifestations" as asserted by the examiner. Applicant has found that all of these conditions can be improved by the administration of ARA. Applicants' invention, concerning the promotion of reproductive success and fertility, as well as promotion of lactation, results from the establishment of a mouse model of PUFA deficiency (discussed on page 6, line 21 onwards). This mouse model has shown the beneficial effects of ARA before pregnancy, during it, as well as after birth. Therefore, one of relative skill in the art would be able to use the information provided within Applicants' specification to treat, or at least ameliorate, conditions which contribute to reduced reproductive efficiency, success or fertility. Additionally, Applicants respectfully disagree that one of relative skill in the art would read the pending claims as encompassing all types of infertility, such as those types which "needs surgical interference" or those types resulting from sterilization. Given the examiner's acknowledgement that the

relative skill of those in the art is high, it is quite clear to those persons skilled in the art would utilize the method of the present invention in those instances that would in fact promote fertility. Applicants respectfully disagree that the present specification has not enabled any other route of administering ARA other than edible formulations. The specification specifically discusses the administration of ARA orally, via pharmaceutical compositions, and edible formulations, including oil formulations. (Specification page 4, line 3 - page 5, line 11). Additionally, ARA is a compound which is naturally found in the mammalian body, although usually in a phospholipids form. Therefore, one of relative skill in the art would understand the present specification as being enabling for all known means of administration of a naturally occurring substance, such as oral formulations, edible formulations, and topical formulations, such as ARA oil formulations which could be absorbed through the skin.

In response to these argument, the examiner position is that the claims are not directed to only conditions caused by PUFA deficiency that are treated by administration of ARA. The claims are broad and encompass all types of promoting reproductive efficiency or success, or fertility as well as preventing conditions associated with PUFA deficiency. Regarding the mouse model applicants referring to on page 6, line 21 onward to show the beneficial effects of ARA before pregnancy, during it, and after birth, the examiner could not locate any reference in the cited text with regard to "before pregnancy" use of ARA on the mouse model. A applicants are referring to the mouse model to show beneficial effects of formulations of the invention including during

pregnancy for both mother and foetus, without mention to before pregnancy effects, i.e. promotion of reproductive efficiency or success, or fertility. Therefore, the specification has not enabled promotion of reproductive efficiency or success, or fertility. Further, the specification has not enabled prevention of all disease conditions associated with an abnormal or low level of PUFA in the blood. Furthermore, the specification has enabled only edible formulation as evident by the examples. On page 3, line 13-17 applicants disclosed edible formulations such as foodstuff including oily food. No mention of topical oily formulation as applicants assert. On page 4, lines 19-30 applicants stated that "Preferably the PUFA is present in an oil." And later in the same paragraph referred to WO 97/13086 for suitable process for preparing PUFA, which reference is directed to oral oily preparation. Therefore, nowhere applicants have disclosed oil formulation for absorption through the skin.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 27 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,200,624 ('624).

US '624 discloses a nutritional supplement comprising ARA and DHA that can be administered to pregnant or lactating human and animal females (title, abstract; col.17, lines 31-38). The supplement comprises 0.1- 5% DHA and 1-15% ARA (col.30, lines 15-22).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-4, 6, 7, 15, 18-21, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,624 ('624) in view of WO 98/16119 ('119).

US '624 teaches a nutritional supplement comprising ARA and DHA that can be administered to pregnant or lactating human and animal females (title, abstract; col.17, lines 31-38). The supplement comprises 0.1- 5% DHA and 1-15% ARA (col.30, lines 15-22).

US '624 does not teach the amount of each of ARA and DHA and their ratios, or the profile of administration of ARA. The reference does not teach clearly the promotion of lactation, but this limitation is implied by the teaching of administering the dietary supplement for lactating human or animal. US '624 does not teach the ARA to be microbial.

WO '119 teaches an edible formulation comprising ARA used as foods for pregnant and lactating mothers (abstract).

It is within the skill in the art to determine the profile of administration of a pharmaceutical formulation and the amount and ratios of different ingredients in order to achieve the desired effect. Thus, the claimed amounts and ratios, and profile of use are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233. It is also within the skill in the art to use formulation comprising ARA and DHA to treat conditions or disorders known to be caused by the deficiency of these fatty acids.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide edible formulation comprising ARA and DHA for administration for lactating and pregnant females as disclosed by US '624, and select

the ARA from microbial origin as disclosed by WO '119, motivated by the teaching of WO '119 that ARA originated from micro-organisms are suitable for human ingestion particularly pregnant and lactating women, as desired by applicants, with reasonable expectation of having edible formulation comprising microbial ARA for administration to pregnant and lactating women that provides the needs of the user.

9. Claims 1, 2, 6, 7, 15, 18 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/16119 ('119).

WO '119 teaches an edible formulation comprising ARA used as foods for pregnant and lactating mothers (abstract).

WO '119 does not teach the amounts and the profile of administration of ARA, or the promotion of lactation in non-human mammal.

The administration to non-human mammal is implied by the teaching of the reference, and does not impart patentability to the claims, absent evidence to the contrary.

The amounts and profiles are not considered critical since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

10. Claims 3, 4,19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '119 in view of Makrides et al.

WO '119 teaches an edible formulation comprising ARA used as foods for pregnant and lactating mothers (abstract).

WO '119 does not teach combining DHA with ARA, or the amount of DHA and the ratios of ARA: DHA.

The amount and ratios do not impart patentability to the claims, absent evidence to the contrary.

Makrides et al. teach method to increase the DHA in breast milk by dietary supplementation of DHA in amount 0.2-1.3 g/day.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to add DHA to the dietary composition comprising ARA for the pregnant or lactating women disclosed by WO '119, motivated by the teaching of Makrides et al. that DHA in the dietary supplement increases the DHA in the breast milk, with reasonable expectation of having a dietary supplement comprising ARA and DHA to be administered to the pregnant and lactating mother to successfully promote lactation.

Response to Arguments

11. Applicant's arguments filed 09/22/2005 have been fully considered but they are not persuasive. Applicants traverse the anticipatory and obviousness rejections of the claims over US '624 by arguing that US '624 provides scant details on how or why DHA and ARA would be administered to the pregnant and/or lactating females. ARA disclosed by US '624 is not microbial. WO '119 does not each that the conditions are

related to low level of ARA. WO '119 does not teach promotion of reproductive success or fertility that usually happens before pregnancy as it is administered to nursing mothers. WO '119 more likely to be administered to humans than to non-humans, with no reference to mammals other than human. Makrides combined with WO '119 do not teach the present invention.

In response to these arguments, the examiner position is that US '624 clearly disclosed "More specifically, the nutritional supplement in accordance of the present invention could be used by pregnant and/or lactating females." Regarding how it is administered, it is clearly given orally, abstract; col.7, lines 4-15; col.17, lines 32-35. Regarding why it is administered, the function is implied by administering the same formulation to the same population, i.e. pregnant and lactating females. Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessary make the claim patentable. Regarding the argument that US 'does not teach microbial ARA, applicant have failed to show superior and unexpected results achieved by using microbial ARA over egg derived ARA disclosed by the prior art. In any event, this argument is moot in view of the combination of US '624 in view of WO '119 that teaches ARA from microbial origin.

Regarding WO '119, the reference teaches administering microbial ARA to pregnant and nursing female. The function of the formulation is implied by administering the same formulation to the same population, i.e. pregnant and nursing females. Regarding promotion of reproductive success, the claim language requires only one

function, i.e. promotion of lactation and/or promotion or reproductivity. Regarding the argument that WO '119 teaches administration to human population the examiner is pointing out the page 7, line 3, where applicants admit the suitability of their formulation for both human and non-human mammals. In any event, it is known in the art to use animal models for biological studies and extrapolate the results to the human being. The active agents are used interchangeably between human and animals since they have similar systems. Burden is shifted to applicants to show that dietary supplement disclosed by the prior art to be administered to nursing women will not be effective in non-human from the same mammalian species.

Regarding Makrides reference, the reference is relied upon for the teaching that DHA in the diet has strong specific effect on breast milk DHA (conclusions). Therefore, the reference would have motivated one having ordinary skill in the art to include DHA in dietary supplement for nursing women. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969). In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious over WO '119 in view of Makrides within the meaning of 35 U.S.C. 103 (a).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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